

Ethical, Translational, and Legal Issues Surrounding the Novel Adoption of Ectogestative Technologies

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Abstract: Increasing numbers of research teams are investigating the feasibility of developing artificial amnion and placenta technology (AAPT), commonly referred to as “artificial womb technology”. This technology, aimed at supporting ex vivo gestation, has not yet been tested in humans, but it has been stated that we are closer to clinical application than ever before as breakthroughs in animal studies demonstrate good proof of principle. With these proof-of-concept models, further dissemination of AAPT as a research modality is expected. In this review article, we consider the ethical implications of the most imminent anticipated applications for AAPT. We focus specifically on the specific ethical complications regarding the improvements this technology may offer to conventional neonatal intensive care, its potential utility in facilitating prenatal interventions, and some of the broader socio-legal implications such as the debates about abortion access and reproductive and gestational choices. We discuss translational and societal questions when it comes to designing and developing this technology, like commitments to value-sensitive design, along with an examination of the legal and moral status of the entity gestating ex utero, which will be relevant for how it ought to be treated in the context of these various applications. From these perspectives, this review identifies the ethical questions that we believe to be most pressing in the development and potential introduction of AAPT, with due attention to their manifestation as translational and legal issues.

Keywords: ectogestation, artificial amnion and placenta technology, artificial womb technology, obstetrics, neonatology, abortion

Introduction

Scientific progress has demonstrated “proof of principle” for systems that can technologically support ex vivo (partial) gestation. Such ectogestative technology (ie, technology facilitating gestation outside the animal body) has been commonly referred to as “artificial womb technology”. Yet, given that it is not so much the womb itself that is replaced by a manufactured apparatus, it has been noted that a more accurate denotation may be “artificial amnion and placenta technology” (AAPT) – even though it should be nuanced that it is also imprecise to assume that the placenta is exhaustively replaced.¹ Indeed, when choosing terms to discuss an emerging biotechnology, awareness of how a choice of words may influence evaluation of this technology may be a relevant factor, and may in itself be subject to debate and evolution.²

In terms of technological evolution, then, varying degrees of success have been reported in the past decade in non-human animal studies, mostly in the lamb model, with the most notable recent advancements being made with pumpless (arteriovenous) extracorporeal designs, using the fetus’ heart to pump the fetal blood from the umbilical arteries.^{3,4} These lamb models go by the more specific names of the EXTEND protocol and the EVE protocol.^{5–8} In both of these models, after an incision is made in the uterus, the lamb fetus is translocated from the ewe uterus to a membrane-sealed ex vivo uterine environment that is filled with a protective artificial amniotic fluid, where continued gestation takes place.

With these recent proof of concept models, further dissemination of AAPT as a research modality is expected, and there are increasing numbers of additional research teams working to develop their own models, for example, in the Netherlands and Canada.^{9,10} In response, it has been stated that we are closer to clinical application than ever before.^{4,11} Still, the concrete emergence of such models for human application remains tentative (indeed, it is not only terminology

that remains unsettled). This does not contradict, however, that bioethical methodology offers tools to critically analyze these perspectives from various angles.¹² More generally, paying close attention to the way new technologies work is a crucial methodological feature of good bioethics scholarship.¹³ It is relevant to understand the function, operation, features, and objectives of emerging technology to identify the ethical issues that it could raise. Meaningful conversation about ethical issues in translation must be a priority when it comes to assessing the ethical, legal, and social issues of novel technological developments such as AAPT. We can anticipate what these issues might be by examining the design and function of the technology in early animal studies, as well as listening to what researchers identify as their objectives in developing AAPT.

We consequently focus on partial ectogestation because, in the way that this technology is currently being developed, it is reliant on the subject having fetal physiology. While current designs have the capacity to take over gestation of a fetus, they are not capable of growing entities from conception to birth “from scratch”, a process that is sometimes called ‘complete ectogenesis’ (denoting that gestation happens from conception to birth completely *ex vivo*; for further terminological discussion of “complete” and “partial” ectogenesis, see reference 14). As we consider below, there may be merits in speculation about a future of complete ectogestation, but we concern ourselves here with the more pressing issues.

First, we consider the anticipated imminent applications for AAPT and its ethical implications by focusing on the improvements this technology may offer as an alternative to conventional neonatal intensive care, as this is the purpose for which the models in development are being designed. We also consider its potential utility in facilitating prenatal interventions as this suggestion has also been made in the scientific literature and there are specific ethical complications that must be noted. In this section, we also consider some questions of design ethics and the importance of ensuring that AAPT is sensitive to social and cultural values. We suggest that these matters should be explored in more depth in future ethical literature. Second, we consider the status of the subject of the artificial placenta. There has been much debate in the bioethical literature about what an entity gestating *ex utero* is, how it ought to be treated, and what it should be called. This debate is important because the legal and moral status of such an entity will dictate how it can be treated and in what circumstances. Third, we outline some of the broader socio-legal implications that are more speculative but that have, however, been the principal focus in much of the bioethics literature. In this section, we outline the principal debates ongoing about abortion access and choices about how to gestate if and when this technology becomes more available. We focus on these social implications because there has been the most debate on these matters in the ethico-legal literature. We note the importance of reflecting on possible longer-term implications of AAPT, but ultimately, we suggest that the other issues we raise in this review are more pressing because they relate to more imminent questions in the development of AAPT.

Anticipated Imminent Applications and Ethical Implications

Improving Neonatal Intensive Care

A prominent translational goal of AAPT is to devise an ameliorated alternative to present-day standards of neonatal care for extremely preterm infants. This is noted as the objective by current working groups.^{5,15} The primary impetus for developing this technique is to salvage morbidity and mortality amongst this population and increase their quality of life.^{15,16} Existing ventilation-based life support for extremely premature infants is believed to have reached its limits. Before the current recognized viability threshold the preterm neonate’s lungs are not sufficiently developed to undergo mechanical ventilation at all (we recognise that a “viability threshold” – a concept from neonatology that determines the boundaries of acceptable treatment in preterm birth – is not a static concept that can be interpreted in different ways, and different countries set their viability threshold at different points; as viability is a shifting criterion, it has even been suggested to consider whether a more robust criterion can be found that is sound and consistently applicable).^{17,18} For those that have the capacity for this process (at or beyond the viability threshold), mechanical ventilation does severe damage to the lungs and can cause long-term disability.^{14,16} Both the EXTEND and the EVE protocol were designed expressly with the intention of circumventing these limitations not by improving existing methods but by better attempting to emulate gestation to allow for proper continued organ maturation.^{5–8} Both studies have produced promising results that illustrate feasibility of extra-corporeal support of preterm fetal sheep and the associated progress that has been made in circuit configuration, oxygenator

technology, and increasing understanding of physiological effects of the artificial environment. Capitalizing on these efforts, it is, according to the current scientific state of the art, feasible to sustain fetal lambs, comparable in size to a 22–25-week human fetus. This is because, to be supported by the models, the subject must have *fetal* physiology (because it is dependent on a heartbeat). AAPT is thus not an integral alternative to pregnancy: An *in vivo* phase in function of embryo implementation and early physiological development precedes the extra uterum gestation phase.¹⁷

In a different kind of venture, researchers have recently communicated that they have succeeded in growing fertilized mouse oocytes from day 0 of development for 11 days in an *ex utero* culture system.^{19,20} This research is not propelled by the goal of improving care for preterm neonates, but is rather aimed at the fundamental study of the earliest stages of embryogenesis – which requires ethical reflection on the future of *ex utero* embryo research. In response, normative translational questions will arise about whether these associated benefits outweigh possible adverse developmental outcomes (and, relatedly, whether/when it is ethically acceptable to terminate subjects of this strand of ectogestative technology).²¹ This prospect, raising theoretical perspectives of so-called complete ectogestation, is currently less imminent than the development of an oxygenated womb-like environment aimed at replacing intensive neonatal care. Not least because it is, in most countries, unlawful to experiment on embryos after 14 days' development, and even if it were not, the scientific unknowns of a gestation outside of the body are numerous since many of these stages of development have never been observed before.¹³ As noted, we have limited scope and choose to focus on those forms of ectogestation that are more likely to come into fruition in the near future. The use of AAPT as an advanced alternative to neonatal intensive care comes with a more pressing ethical urgency given that it is likely to be developed first, propelled by a clear clinical objective.²²

Recognising a moral duty to improve morbidity and mortality rates in neonatal intensive care and assuming AAPT will effectively help facilitate improvement, there is a consequent *prima facie* ethical reason to develop this technology. This might be thought particularly true in cases where premature babies are likely to be treated with existing procedures in neonatal intensive care, with limited utility at addressing underdeveloped physiology and high risk of infection, so that death remains likely. In these cases, premature babies are suffering. There might thus be an ethical imperative to improve treatment options that mean less suffering and better odds of survival. This observation does not necessarily mean that this moral motivation is a sufficient condition for clinical application.^{5,8,10} It should be noted from the outset that this avenue should not unconditionally be framed as a mere continuation of already existing neonatal intensive care. Whereas present-day infant incubators support neonates with bodily functions they cannot yet perform adequately for themselves, AAPT supports extracorporeal continued fetal development “as if the neonate had never been born” (even though it has been translocated from the uterus of the body of the pregnant person).^{1,15} This distinction is morally relevant, as it may have translational, clinical implications: framing AAPT as a continuation of conventional neonatal intensive care has the (dubious) connotation that it can be introduced as an innovative technology, not as experimental research.²³ This connects to the prospect that the experimental use of AAPT will entail technical and medical risks very different from those in conventional care.

Despite encouraging results in animal models, challenges remain, and even if additional research may reduce these risks, translational obstacles should be considered, not in the least because of residual “unknown unknowns” and concerns about parents-to-be feeling pressured to consent to experimental procedures.²³ Current AAPT-models have not yet been tested on humans, and due to substantial physiological differences between these animal models and humans, similar results cannot yet be expected in the human model.²⁴ In that respect, research on non-human animals with physiologies more similar to humans has been suggested.²³ The most recent steps in that direction, are emerging studies done on pigs, which closer mimics human size, brain maturation and physiology of the umbilical cord.²⁵ This offers a realistic model that can help facilitate the clinical translation of AAPT technology, specifically in the context of providing a “physiologically appropriate form of intensive care to the extremely preterm infant”.²⁵ As has been noted in biotechnological contexts different from ectogestative research, there is ethical work to be done to analyze proportionality and subsidiarity when doing translational research with different types of animals in function of expected benefits of human application.²⁶

Besides the differences between non-human animal models and human models, substantial obstacles for clinical translation are the analysis of organ development, adequate cannulation and functionality of catheters, oxygenator

miniaturization, the limited scope of placental functions that current models can perform, administration of appropriate nutrition and hormone levels, the stability of the circuit flow and the related issue of dosing paralytics to minimize fetal movement that limits circuit flow.^{3,27} In light of these challenges, and provided that this technology is aimed at reducing extreme preterm morbidity and mortality, a crucial ethical question that will have to be answered, is how much better – compared to present-day standards – the expected results will have to be. Despite these challenges, equity financing for clinical translation was secured in 2022 by a team working in Philadelphia, which we believe makes the ethical issues in clinical translation pressing.²⁸

It will be a difficult matter to isolate the appropriate clinical population. For example, it might be argued that it is arguable that “pre-viable” entities (at or below the 22-week threshold) might be more ethically appropriate since they are not being denied conventional treatment with a reasonable chance of success and it is easier to establish equipoise.²³ Researchers have indicated, however, that experimental use of AAPT does not preclude the subject from being removed for treatment in conventional care if it does not appear to be working better, which addresses some of these concerns. There are equally concerns about using entities that would not otherwise be treated since there is a much greater likelihood that the entity will have its suffering prolonged without utility.²³ These will be complicated matters for ethics boards deciding on human trial conditions.

Importantly, while these questions about safety for the “future child” are cardinal for biomedical ethics, a focus on assuring these aspects must not fail to acknowledge the ethical significance of how this intervention primarily impacts on the (formerly) pregnant person. The translocation of the fetus to the ectogestative milieu requires major surgery, comparable to, but likely more invasive than a caesarean section.^{29,31} As the incision happens on a comparatively smaller uterus, with the correspondingly more onerous venture of cutting through muscular tissue, the risk of excessive bleeding and surgical complications will likely be greater. Thus, as has been described by several authors, this comes with perioperative risks to the pregnant person (which may include, in case of subsequent pregnancies, an increased risk of uterine rupture and abnormal placental implantation).^{29,31} For this reason, it has been stipulated that the alternative of vaginal delivery (while preventing transition to neonatal physiology) will have to be considered, with the relevant comparative evaluation in terms of feasibility, safety, and choice (of note: the possibility of transfer from the mammal womb through the birth canal without exposure to ambient conditions is effectively being researched).³² Further, the physical impact of the surgical translocation may possibly compromise a person’s eventual later reproductive trajectory and is generally compounded by the ethical challenge to justify whether the burdens are proportionate to the envisaged clinical benefits.^{33–35} We will return to the moral relevance of this surgical intervention below, when we discuss AAPT as a means to advance prenatal therapy. Yet, it may already be noted that the ethical discussion of ectogestation’s potential to ameliorate neonatal outcomes in case of extreme prematurity, along with moral questions of what it means for medical personnel and future parents to “do good” in this respect, will be complicated by the ambiguous perception of the invasiveness of the surgical intervention and considerations of the pregnant person’s autonomy.³³ This also means that considerations of obtaining a proper informed consent from the person on whose body this surgical procedure is performed will be key, alongside attention to possible psychological effects.

One possible consideration will be whether the limited physical contact post-intervention, due to containment in the ectogestative chamber, may impact the parent and/or the infant later in life.^{16,35} Indeed, most attention in terms of (harmful) psychological effects, has been “offspring-centered”, in which case it is hard to determine not only the scope of such presumed risks for the future child’s psychological development, but also whether such concerns would be graver than the benefits that ectogestative technologies could bring (which is at least complicated by the fact that research (ie, animal and/or laboratory) models may not be satisfactorily translatable to provide such insights).¹⁴ Less attention is paid to the adults’ psychological perspective, although some speculations have been noted about relational-psychological effects due to reduced sensory experiences of pregnancy, which – if a problem at all – would primarily pertain in the context of “full ectogestation”.³⁶ That said, it is known, for instance, from the context of premature birth, that people who have birthed and intend to parent often experience sadness, disappointment and guilt when they cannot hold their child, and that the risk of postnatal depression is significantly higher following preterm birth.^{37,38} While the psychological impact of ex vivo gestation is at least to a certain degree speculative, considerations like these from NICU might nonetheless give some guidance in the context of “partial ectogestation”, even though this also entails that such

observations are not unique to the context of ectogestation. It might be noted that such possible psychological concerns should not be exaggerated and need not be a sufficient ethical argument against the employment of AAPT. This does not contradict, however, that these considerations in terms of psychological wellbeing have some bearing on the ethics of this (potential) practice, and that these reflections (including those pertaining to surgical extraction for ectogestation) also shape the ethical issues that surround the possible application of AAPT as a facilitator of prenatal therapy. We, at the very least, have obligations to consider those who may be affected in the development of ectogestation and consider strategies to minimize any of the harms or difficulties they may experience in that process.

Before moving onto that discussion of prenatal interventions, we make the final observation that following the clinical translation of this technology *how* it is made routinely available and whether this is accessible to all is a salient ethical concern. As Horn and Romanis have highlighted, even in health-care systems that are free at the point of access, access to certain treatment is often disparate, particularly so in instances where treatments are resource intensive.³⁹ They thus speculate that, as with neonatal intensive care, eg, ECMO, the National Health Service will concentrate the service to only a few hospitals so that expertise is concentrated, and expensive resources are maximized.³⁹ This raises questions about whether the technology will be scalable, and whether there will be any meaningful access for people in smaller cities/rural areas where there is a lack of relevant expertise or equipment, for example, in the health professionals who first attend an individual in premature labour outside of the specialist AAPT treatment units. Similar disparities will likely emerge, much more drastically, in countries without free healthcare where access to this technology – that can mean the difference between life and death for premature neonates – is simply unaffordable for most.³⁹ These authors similarly raise the concern that since premature delivery is more likely to occur in individuals who are structurally disadvantaged, potential access disparities in future should also be thought of as a translational issue to avoid the injustice of the group who bear the brunt of the risks in testing and developing AAPT for human use, while being less likely to benefit from its use once it is determined safe.²²

Facilitating Prenatal Interventions

While not considered the primary aim, the idea is gaining traction in present-day accounts that AAPT could improve the feasibility and safety of targeted prenatal therapy.^{33,34} In earlier discussions, interventions to correct non-lethal conditions have been named in this context, like surgery for hydrocephaly or cleft palate.⁴⁰ Here one could also count the satisfaction of the future parents' wish for a healthy child, and compliance to the presumed duty of beneficence towards the future child among the possible ethical motivations.³³ This also has an influence on design questions, in the sense that it has been suggested that the administration of fetal therapeutic surgery will require that the subject is safely manually accessible.³²

It is important to note that it is believed that such corrective procedures might be performed without risk of maternal morbidity.^{34,40} However, even if ectogestation-aided prenatal treatment (EAPT) could facilitate interventions by allowing it to happen outside the strict intrauterine milieu, this does not necessarily yield the normative conclusion that such usage would be ethically commendable as it may, by the same token, exacerbate potential tensions between presumed moral obligations towards the fetus and the pregnant person. While there is some consensus on the view that, if a pregnancy is set to lead to a child, certain beneficence-based responsibilities exist vis-a-vis this future child, the decision whether to undergo the surgical translocation in case of ectogestation is an extension of this principle of respect for personal autonomy and some authors would consider this decision for the benefit of a future child a supererogatory act.^{34,41–44} It is, in this respect, crucial to grasp the above-mentioned caveat that the surgical intervention on the pregnant person's body is morally relevant, not only because of possible adverse consequences, but also, more generally, in view of their physical integrity, the related right to refuse interventions, the value of autonomy and personal values vis-à-vis pregnancy.^{33,45} This ethical matter cannot, in other words, be reduced to physical risks. One should also consider an individual's choice for a desired mode of delivery as a central aspect of this person's conception of the good.^{33,44}

There is, relatedly, moral appeal in warnings about increasing pressures on pregnant persons.⁴⁶ With the perspective of EAPT, one might worry that tradeoffs between assumed obligations of beneficence towards the future child and the interests of the affected individual become more complicated. This is not simply an extent of the so-called technological imperative but is also tied to the relationship between ectogestative technologies, their effect on viability and

ethical guidelines that inform neonatal care.⁴⁷ There has been one (small) study that indicated that Australian medical professionals perceived that the availability of ectogestation would shift the “gestational age of viability” in such a way that might influence their treatment decisions.⁴⁸ To the extent that existing guidelines in neonatal care subscribe to directive counselling in favor of medical interventions for fetal benefit from the moment of viability, and to the extent that AAPT might push the limit of viability lower, one may have to contemplate a potential future dynamic towards routine directive counselling for prenatal intervention when EAPT becomes possible.^{24,33,49} Adkins warns that ectogestation may change the balance in the doctor-patient (here being the pregnant person) relationship to the extent that doctors may assume greater authority in the management of her pregnancy.⁵⁰ It is worth stressing that in that regard one should pay continued ethical attention to socio-cultural dynamics and stratified structural contexts that shape choice and agency, propelled by technological developments, that may accrue pressures on pregnant persons.^{35,51–54} As mentioned above, the concern that it is often disadvantaged groups that are more likely to experience preterm birth and need prenatal care, is particularly important as this technology is developed.^{22,39} Some have suggested that we must be attentive to this in the development of this technology to ensure that such stakeholders are centred rather than exploited.^{22,39} This does not only hold for envisaged benefits for facilitating prenatal therapy, but also for less imminent speculations about how AAPT might in the future be employed to secure an optimal fetal milieu – in which case ethical concerns arise about how especially disadvantaged groups may experience pressures in that direction.^{14,47,51–53}

This also requires careful consideration of which conditions may be reasonable candidates for such interventions. It is fair to flag that more ethical work is required to approach the open ethical question of how to balance the risks that come with EAPT against beneficence-based obligations towards the future child. It can indeed be noted that present-day clinical care has already incorporated surgical interventions that shift aims from “saving the fetus” to “improving the health prospects of the future child”, which is evident from performance of in utero surgery to correct myelomeningo-coele for instance.⁵⁵ Ethical guidelines from the current practice of fetal therapy may be a relevant starting point for how to evaluate proportionality when interests of the future child and professional directiveness are considered. In the current context, this amounts to evidence-based treatments to save the future child from significant and irreversible damage, without exposing the pregnant woman to serious burdens.⁵⁵ Indeed, in actual reality, balancing “the claimed benefits of fetal intervention against the inherent side effects of the surgery” already turns out to be very difficult.⁵⁶ The mixed perception of the invasiveness of procedures like caesarean sections makes the ethical discussion of EAPT, and the decision for which interventions it would be ethically apt, even more complex (which, again, is not limited to considerations of physical integrity).³³

One might remark that pregnant persons may be willing to undergo translocation surgery and associated burdens, not just in function of a personal desire to have a healthy child, but that such willingness may also be an exponent of admonitions to act as a good parent-to-be. A choice to the contrary, when continued ex utero gestation is available, may lead to moral blame.^{57,58} While autonomous choice is naturally structured by factors like social relationships, expectations, and intersectional conditions, we should not simply accept the way in which technological and socio-cultural influences shape such demands on pregnant persons, the subsequent choices they make, and how this relates to moral blame. That said, facilitating choice, while considering an individual’s circumstances, is ethically important as an exponent of the *prima facie* value attached to autonomy, which can only potentially be justifiably overruled in view of “good moral reasons” reflecting other basic ethical principles like safety and equity of access.^{35,44,59}

Societal Dialogue and Value Sensitive Design

While the time frame for the clinical introduction of the recent proof of concept studies remains unclear, it is nonetheless to be expected that they will induce a further dissemination of research into the feasibility of potential human application. Future research trajectories may range from securing survival at the limit of viability to completely mimicking gestation. As the former is expected to be more imminent, related questions will at least have to be answered about how “securing survival” is to be understood: eg, how long should the gestated entity survive for the intervention to be considered worthwhile or successful, where should the bar of expectations be put compared to current outcomes of neonatal intensive care, and what and whose understanding of quality of life must be adopted in these considerations?²³

In the light of such translational questions, authors have postulated that societal dialogue on the development and implementation of ectogestative technologies will be important throughout the entire research and design process.^{16,32} The justification of such stakeholder involvement hinges on the expectation that the technology may not only change high-risk newborn care, but also moral perceptions of pregnancy, birth, motherhood, and parenthood more generally.^{16,32} One may expect conflicting moral views on the development and implementation of this technology but considering the proposed *prima facie* (clinical) benefits, it may be part of a “prudent path forward” to organize dialogue between various stakeholders to map those diverse perspectives and avoid that those potential benefits get lost due to a lack of public trust. Building public and moral consensus can be viewed as a function of ethical negotiation and (laborious) political processes, which may, based on realistic expectations, culminate in acceptance of emerging AAPT, though not without heedfulness concerning ethical, social and legal concerns.

Scholars have argued that such dialogue should be comprehensive, both in terms of input to the technology’s design and in terms of who participates in this process.^{16,32} It has been argued that members of the public should be included as dialogists throughout the research and development process, given the technology’s potential fallout on social views regarding, eg, pregnancy and motherhood.^{16,32} Such ambitions are then formulated as a matter of “value-sensitive design”.¹⁶ As any other technology, ectogestative technology incorporates and propagates value-laden choices. This is inherent not only in the decision to approach a “problem” in one way rather than another, but indeed also in the basic judgment that the phenomenon at hand is a “problem” at all. We suggest that matters of design are in need of more attention in the ethics discourse about this technology.

Status of the Subject of AAPT

There is ongoing academic debate about the legal and moral status of the subject of AAPT. Following the publication of the first results from EXTEND therapy and the significant attention it attained in the public sphere, a body of ethico-legal literature more focused on partial ectogestation began to emerge, with a central question how to conceptualize the subject of AAPT. While many questions about the legal and moral status are still unanswered, they will be determinative of a lot of the issues outlined in this review. For example, if the subject of AAPT has the rights of a child it could only be treated in its best interests and the design choices mentioned above will have to facilitate maximising the best outcomes over facilitating parental involvement in the process where these come into conflict. On the other hand, if the entity has legal rights like that of a fetus, medical research could be permissible where the formerly pregnant person consents even if the other genetic progenitor does not.²³

Some commentators have argued that there is a clear conceptual difference between AAPT and conventional neonatal intensive care because of differences in the function of these technologies, and the behavior, physiology, and physicality of the subject.^{1,13,15,17,60–62} These differences result from the fact that AAPT facilitates gestation *ex utero* rather than forcing the entity to make the transition to physiology that is interactive with the external environment.^{1,61} This is contested by commentators who believe that the subject of AAPT is a “newborn” because it has been delivered from a pregnancy.^{63–65} However, commentators who believe that ectogestation is distinct maintain that there is a difference between an entity being delivered from a pregnant person and being “completely born”.^{1,61}

The suggested value in a unique and separate concept, is to provide “useful clarity and an accurate descriptor.”¹⁵ Romanis, in first outlining the conceptual distinction between AAPT and conventional care, suggested the neologism “gestateling” to describe the entity undergoing gestation *ex utero*.¹⁵ Other scholars have used their own distinct terms to describe the entity, eg, “fetonate”.⁴ Interestingly, terminological choice might be context dependent. “Gestateling”, for example, was coined in an ethico-legal context to distinguish it from existing terms with normative connotations (like “fetus”, “newborn”, “infant”), which “do little to emphasize the uniqueness of the gestateling”.¹³ In contrast, authors with a clinical background might be more concerned about ensuring that the term is easily recognizable to putative parents who may need this technology, and particularly those who may be the first consenting experimental users. While the matter of identifying an appropriate descriptor might seem like a “mere” semantic issue, we suggest that it plays a relevant role in appropriately managing expectations about the technology – in reiterating how it is different – to all stakeholders. This may be important not only in ethical conversation, but also in how information about the technology is communicated to the public so that it is understood, and also to putative parents who may use the technology.

Whatever unique term is adopted, conceptual clarity usefully allows us to highlight the unique ethical questions surrounding the treatment of this entity. How the subject of AAPT is categorised matters, as the law currently constructs a clear binary at the beginning of life in many jurisdictions: eg, a “fetus” has limited legal rights and a “newborn baby” has all the same rights and protections as an adult person.⁶² Notably, commentators who have defended the gestateling as a unique entity have not specified what the moral significance of the entity might be, with some explicitly noting that there are more important prevailing ethical considerations, eg, the pregnant person who has a clear moral worth.^{1,60,61} That said, there is an acknowledgement that the uniqueness of the gestateling might mean that there is scope for a conversation about what kinds of rights and entitlements it might have, eg, it is intuitive to assume it might have more protection than a fetus since this would not impact on the bodily autonomy of a pregnant person (once it is in the artificial placenta), but also that it should have less protection than a completely born baby since it is not similarly socially situated.¹³ In some jurisdictions it is arguable that the ectogestative subject does not meet the threshold for the legal protections of a newborn baby as the law is currently constructed, though this is a disputed conclusion.^{23,64}

Most academic discussion about how to treat the subject of AAPT tends to focus on the ways in which it might be different from a fetus, eg, some have argued there may be limited justification for aborting it, or if it can this should be a decision for *both* genetic progenitors together.^{66–68} Rodger et al argue that “gestaticide” (the killing of a gestateling) is morally equivalent to infanticide, largely because they consider that the assumed gestateling is born in a “straightforward sense” (thus implying that terminating it is as morally serious as infanticide).⁶⁶ Amongst those scholars that take the gestateling to be conceptually distinct, there has not yet been a developed discussion about how there might be circumstances in which it might be justifiable or appropriate to treat this entity differently from a newborn, but these circumstances are imaginable. In many jurisdictions, it is unlawful to actively end the life of a newborn even if it is suffering (the Groningen Protocol in the Netherlands is an exception that posits that in certain situations and subject to strict criteria active ending of life on infants might be appropriate)⁶⁹ but one could imagine that if an entity were gestating outside of the body and there was evidence that it would not be able to make the transition to neonatal physiology without only suffering, then there might be justification to “turn off” AAPT prior to transition to prevent that suffering. The ending of the gestateling’s life in this instance might not be construed as “killing” but rather “letting it die” since the process of creation is being terminated, rather than the life functions of an entity post-creation being interfered with. While many commentators describe the distinction between killing and letting die to be morally immaterial, this distinction is taken to be relevant in healthcare practice (it has become a key feature of legal decisions about end-of-life treatment in some jurisdictions, for instance, in England and Wales per *Airedale National Health Service Trust v Bland* [1993] AC 789).⁷⁰ We anticipate that more academic discussion on such, and other similar, circumstances is necessary and insist that such conversation should be appropriately attentive to disability rights. The matter of the legal status of an entity gestating ex utero needs resolution for practical reasons such as who makes a determination about treatment and what kind of liability might accrue and by whom where treatment goes wrong.^{13,50,62,71} It is clear that further interrogation of these issues is necessary.

Broader Socio-Legal Implications: Speculative Scenarios

For the sake of completeness, in this section we explore some of the conversations in the literature that consider ectogestation in its more speculative form. We emphasize that the use of this technology to “end abortion” and “secure gender/sex equality” should be approached with caution as such suggestions should be thought far removed from contemporary realities.³⁹

Abortion

It is noticeable that there is more literature on the impact of this technology on abortion than on any other issue surrounding the development of this technology. Much of this literature focuses on the ethical question about the extent to which abortion would or should become impermissible if AAPT could continue gestation ex utero. There was a considerable body of literature on the permissibility of conventional abortion long before current animal prototypes establishing “proof of principle”.^{59,72,73} There has also been a growing body of literature since 2017.^{74–78} These recent bioethics papers all make a similar argument to those before 2017 positing that with the advent of this technology we

could reach a “solution” to abortion: whereby pregnant people could end their pregnancies, but this need not necessarily result in fetal death. In line with this, Di Stefano et al reported that uncertainty exists among their surveyed sample of Australian obstetricians and neonatologists about whether ectogestative technology should result in restrictions in access to elective termination of pregnancy.⁴⁸ The more recent arguments made by scholars such as Stratman, Simkulet and others are based on the same premises as those in earlier work.^{77–80} At their root, these claims stipulate, as put by Singer and Wells, that

Freedom to choose what happens to one’s body is one thing; freedom to insist on the death of a being that is capable of living outside one’s body is another thing.⁸¹

The ethical underpinnings of the so-called “right to the death of the fetus” has been hotly debated, and it is fair to say that the moral belief that pregnant people would be morally compelled to transfer the fetus to an extracorporeal gestative device, rather than seek termination of the fetus, has some traction in these discussions.^{76,82} In response to such claims, there is a body of feminist literature that explicitly defends the necessity of conventional abortion (resulting in fetal death) following the advent of partial ectogestation and even if AAPT advanced to the point of being capable of facilitating complete ectogestation.^{17,22,23,30,45,47,51,83–85} This body of work considers the bodily autonomy of pregnant people and the realities of transfer to AAPT, but also broader arguments of reproductive autonomy and sex/gender equality.^{17,22,23,30,45,51,86} In relation to the immediate development of this technology, it is important to note that it does not have the capacity to be a functional replacement for medical or surgical abortion – which is safe and can take place early in a pregnancy.⁴⁵ It is hard to ignore the fact, however, that abortion rights may be impacted by AAPT in countries where abortion rights are centered on viability, if it becomes capable of supporting entities more reliably earlier in gestation.⁴⁵

That this debate is consistently reproduced in the literature speaks to the socio-political emphasis placed on abortion as a “moral problem.” This is not without root in the real world: the US Supreme Court has just, at the time of writing, announced the end of the right to abortion as a recognized part of the constitutional right to privacy.⁸⁷ There are currently consequent anticipated abortion bans across half of the country. A hostile environment for abortion rights is not just a US problem: there are many countries across the world where abortion is unlawful in most cases. Several scholars have argued that against this context it is time that we move away from discussing “abortion as a problem” and explicitly focus on AAPT not as a technology to facilitate the end of reproductive rights but instead as something with the capacity to help parents who risk losing their wanted offspring.^{22,39,88} Some may argue that there is always space for a speculative literature considering the permissibility of abortion if AAPT-fetal transfer were ever to become comparable to an abortion, however Romanis and Horn have argued that

Responsible literature should begin ethical assessments of the future implications of ectogenic technology from a place of affirming contemporary (and future) abortion as essential healthcare.²²

In addition to the ethical arguments, there has been reflection about how abortion law might be impacted by AAPT. The law in many jurisdictions is framed around viability (although this is no longer the case in US constitutional law); dictating that abortion is easier to access before the fetus becomes “viable” and more difficult to access after “viability”.^{17,51,89–91} Viability is usually taken to mean that the fetus has the ability to survive outside the womb.⁹² Romanis has argued that, if viability thresholds remain a central concept in regulation, this concept needs to be more precisely understood – as the ability to survive ex gestation – to reflect the purpose of the viability threshold.¹⁷ Räsänen reached a similar conclusion.⁹¹ Horn, and subsequently Romanis, have gone further, however, to suggest that this technology adds to the case for the decriminalization of abortion, and thus the end of the central role of viability in determining the legal permissibility of abortion.^{17,51} Horn argues that viability deployed in regulation will always come to limit abortion access whatever measure is adopted and these limitations fail to uphold the reasons why abortion is important for individuals.⁵¹ Romanis argues that AAPT illustrates the conceptual (and doctrinal) incoherence of viability thresholds.¹⁷ Reflections on how existing legal frameworks are impacted by developments such as AAPT does help us to anticipate potential upcoming challenges of the implementation of partial ectogestation and what law reform may be necessary.

Reproductive Autonomy and Equality

There is a large body of literature in which ectogestative technology is framed as an innovative, elective option to people who wish to procreate, but for whom pregnancy is impossible, medically discouraged, or undesired. This includes reproductive use by persons with or without medical indications, both singles and couples, regardless of gender or sexual orientation.^{44,93–97} These perspectives either heavily rely on the less imminent perspective of “full ectogestation”, or map onto the speculative outlook of employing AAPT to redress the physical, social, financial (or other practical) burdens associated with a complete pregnancy and childbirth (given our primary focus on translational and ethical issues in adopting ectogestative technology we refer for further reading to the overview presented in reference 14).

Access to obstetric technology is presently mainly medically controlled, which might be a reason not to expect such an employment of AAPT momentarily, alongside the expected high financial costs and the earlier mentioned fact that the associated surgical intervention may for some people be a disincentive.^{31,35,98} Furthermore, some commentators have noted the problem with considering this technology as a “solution” to the burdens of pregnancy and childbirth. It could limit reproductive choice by making it harder for people to opt into pregnancy where they want to have this experience and/or result in a worsening of prenatal and birthing care.^{39,53,71,99} Such factors would need to be considered in determining how to frame the availability of the technology. Finally, perhaps most determinative on the matter of access, medical professionals are likely to argue that the minimal comparator for elective use of this technology should be standard human pregnancy, which is a far cry from the current proof of concept (whereas the comparator for potential emergency use in neonatal intensive care would rather be the current poor prospects of extremely premature infants with standard care). Consequently, many have suggested that the technology ought only to be available for “medical need”.¹⁰⁰ “Medical need” is often believed to function as a yardstick to evaluate whether there is a strong ethical duty to offer a certain technology.^{101,102} Though what “counts” as a medical need can be contested. If a particular claim is regarded as “desire-based” it is often considered normatively inconsequential and an illegitimate basis for claims on others. However, this is a philosophically complicated matter, and it is ethically unclear why desire-based claims of which the goal is regarded valuable and acceptable, should not be considered a serious contender for third party support.¹⁰³

We do not suggest that the physical, social, or moral reasons to seek such use of AAPT would be trivial. In normative terms, a major part of this debate effectively hinges on the idea that the technology could enable people to pursue their preferred parenthood project, including discretion about how to achieve it and potentially advance equality amongst people in terms of who carries the physical burdens of these reproductive choices.^{94–97} Here as well, respecting autonomy to protect personal choice about reproductive projects should be balanced against other moral considerations like equity of access.^{35,57}

For our present purposes, it is most relevant to consider these (albeit speculative) perspectives through the lens of so-called “soft impacts” as part of a comprehensive technology assessment that includes awareness of wider concerns, such as how this emerging technology might affect existing practices, routines and norms.¹⁰⁴ This includes attention to how visions of ectogestation may have a fallout in terms of how “responsible motherhood” is conceptualized (think of admonitions to secure an optimal gestational milieu), how we deal with existing reproductive stratification (think of racialized and gendered disparities), and how existing frameworks and practices may seem ill-equipped to respond to lived experiences of pregnancy and maternity (think of challenges in terms of workers’ rights during pregnancy).^{22,33,35,39,53,58,105,106} While such soft impacts are largely hypothetical and difficult to corroborate, it is important to delicately include them in ethical assessments to increase awareness and avoid later public discontent. Theoretical scenarios for ectogestation as a reproductive option for diverse motivations (eg, freedom-and/or equality-promotion) may offend the moral convictions of some while pleasing the views of others.⁵³ Moral bewilderment or excitement does not in itself conclude the ethical acceptability of such scenarios. Instead, ethical assessment requires balanced consideration of concerns and realistic expectations of AAPT in advance of its development, and careful communication to avoid false hope, moral panic, and loss of trust to the detriment of recognized potential benefits.^{13,39}

Finally, we note that these considerations are also likely to have legal relevance – for example, some commentators have explored how legal frameworks can come to limit access to reproductive choices like ectogestation in place of pregnancy.

These may be direct legal barriers, for example the law being written in such a way that prevents a person from opting out of pregnancy – even in circumstances that do not harm a fetus – without medical justification (as it may be in England and Wales).³¹ Similarly, there may also be indirect legal barriers that need dismantling – for example, the way that employment law frameworks are constructed in the European Union may prevent workers from opting for ectogestation because it might limit their protection from discrimination or their leave entitlements.³⁵ These examples illustrate, again, the importance of thinking about AAPT in the context of existing legal frameworks to anticipate forthcoming challenges.

Conclusion

AAPT is a sought-after medical development for the many unique benefits it can bring, most particularly in reducing neonatal and maternal morbidity and mortality. There are studies demonstrating very good proof of principle in animal models, most notably the EXTEND system and EVE platform. There are increasing numbers of research teams working around the globe to develop their own models based on this success. Given the clear clinical objective of researchers and this technology's medical utility, we can anticipate good progress will continue to be made towards the development of AAPT, towards human testing and then to clinical translation.

The coming development, testing, and translation of this technology involves myriad ethical, social, and legal issues. The artificial placenta is not just a clinical or medical engineering challenge. It raises matters for consideration that need input from bioethicists, lawyers, and potential service-users. In this review, we did consider some of the more speculative prospects of AAPT that the bioethical and legal literature has thus far been more focused on. We considered why it is useful that some anticipation is undertaken as the technology comes to fruition; however, we concur with the feminist literature that has called for “more grounded” ethical reflection on AAPT.^{22,39} There is a need to be attentive to the realities of how the technology as it is being designed is intended to function and how it *should*. We focused on some of those issues that we believe to be most pressing in the development and immediate testing of AAPT. These matters are all live questions: how do we identify the appropriate target clinical population for testing? In what circumstances might we be able to get proper informed consent from the pregnant person? What values do we prioritize in the design and function of the device? What should the technology look like? There is a growing and evolving body of bioethical, legal, and sociological literature exploring such questions, and this should be attended to by those involved in the research and development of AAPT.

Disclosure

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